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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,062	08/25/2005	Harold Philip Swerdlow	2713-1-1032PCT/US	4695

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KLAUBER & JACKSON  
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HACKENSACK, NJ 07601

EXAMINER
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WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/547,062	<b>Applicant(s)</b> SWERDLOW ET AL.	
	<b>Examiner</b> Ethan Whisenant, Ph.D.	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1634

**NON-FINAL ACTION**

1. The applicant's Preliminary Amendment filed 25 AUG 05 has been entered. Following the entry of the Preliminary Amendment, **Claim(s) 1-20** is/are pending. Please note that the claim set filed 25 AUG 05 has two Claim 5s and no Claim 4. Accordingly, in accordance with rule 126 (i.e. 37 CFR 1.126) the claims have been renumbered as Claims 1-20 as set forth below. The applicant is required to adopt this claim numbering.

Old #	1	2	3	5	5	6	7	8	9	10	11	12	13	14	15	16
New #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Old #	17	18	19	20
New #	17	18	19	20

**35 USC § 112- 2nd Paragraph**

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

3. **Claim(s) 1-20** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1** is indefinite because the phrase "the reference one or more SNPs" lacks proper antecedent basis.

**Claim 6** is indefinite because the phrase "the sequencing reaction(s)" lacks proper antecedent basis. Also the phrase "detecting the incorporation of bases into the immobilised oligonucleotide to determine at least the unique coding sequence.

**Claim 14** is indefinite in view of the limitations "5'-iodide and 3'-selenophosphate". The examiner is unfamiliar with these terms, therefore it is unclear to the examiner what metes and bounds these terms encompass.

### 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

### **Claim Rejections under 35 USC § 102**

**6. Claim(s) 1-3, 8-12, 15** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al. [US 4,988,617 (1991)].

Landegren et al. teach a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claims 1-3, 8-12 and 15. Please note that in Landegren the first oligos are the adjacent probes and the second oligos are the 5'-biotinylated target probes. See for example Figure 1.

### **35 USC § 103**

**7.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**8.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

### Claim Rejections under 35 USC § 103

9. **Claim(s) 4 and 16-17** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al. [US 4,988,617 (1991)] as applied against Claim 1 above and further in view of Landegren et al. [US 2005/0287526 (2005)].

**Claim 4** is drawn to an embodiment of Claim 1 wherein said each of the oligos of the first oligonucleotide set includes a hairpin. **Claim 16** is drawn to an embodiment of Claim 2 wherein said each of the oligos of the first oligonucleotide set includes a hairpin. **Claim 16** is drawn to an embodiment of Claim 2 wherein said each of the oligos of the first oligonucleotide set includes a hairpin.

Landegren et al. in the 617' patent teach a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claims 4 and 16-17 except these authors do not teach an embodiment wherein the first oligonucleotides are hairpin oligonucleotides. However, as evidenced by Landegren et al. in their US patent application document (i.e. US 2005/0287526) the use of oligos comprising a hairpin structure in a ligation based assay was known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize the hairpin probes of Landegren et al. in place of the convention oligonucleotide probes disclosed by Landegren et al. in 617'. The ordinary artisan would have been motivated to make the modification of the Landegren et al. method disclosed in the in 617' patent in light of the teachings set forth in paragraph [0052] of US 2005/0287526 wherein these authors teach that the use of hairpin probes favours the ligation of matched probes over misligation of mismatched probes in ligation based assays.

**10. Claim(s) 5-6 and 18-19** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al. [US 4,988,617 (1991)] as applied against Claims 1-3 above and further in view of Brenner et al. [US 5,846,719 (1998)].

**Claim 5** is drawn to an embodiment of Claim 1 wherein said label is a unique coding sequence of nucleotides in said first oligonucleotide set. **Claim 18** is drawn to an embodiment of Claim 2 wherein said label is a unique coding sequence of nucleotides in said first oligonucleotide set. **Claim 19** is drawn to an embodiment of Claim 2 wherein said label is a unique coding sequence of nucleotides in said first oligonucleotide set.

Landegren et al. teach a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claim 5 and 18-19 except these authors do not teach an embodiment wherein the label of said first oligonucleotide set is a unique coding sequence of nucleotides. However, as evidenced by at least Brenner et al. the use of oligonucleotide tags (i.e. a unique coding sequence of nucleotides) as well as labeled oligonucleotide tag complements was known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the method of detecting an oligonucleotide disclosed by Brenner et al. for the method of detection disclosed by Landegren et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

**11. Claim(s) 7 and 13** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al. [US 4,988,617 (1991)] as applied against Claim 1 above and further in view of Balasubramanian et al. [US 6,787,308 (2004)].

**Claim 7** is drawn to an embodiment of Claim 1 wherein said oligonucleotides are immobilised on said support at a density that allows each immobilised oligonucleotide to be individually resolved by optical microscopy.

Landegren et al. teach a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claim 7 except these authors do not teach an embodiment wherein the oligonucleotides are immobilised on said support at a density that allows each immobilised oligonucleotide to be individually resolved by optical microscopy. However, as evidenced by at least Balasubramanian et al. the immobilization of oligos on a solid support at a density that allows each immobilised oligonucleotide to be individually resolved by optical microscopy was well known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the method of immobilization disclosed by Balasubramanian et al for the method of immobilization disclosed by Landegren et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

**Claim 13** is drawn to an embodiment of Claim 1 wherein the first and second sets of oligonucleotides are contacted with said genome under conditions that permit non-enzymatic chemical ligation.



Landegren et al. teach a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claim 13 except these authors do not teach an embodiment wherein the oligonucleotides are ligated using non-enzymatic chemical ligation means. However, as evidenced by at least Balasubramanian et al. in the 308' patent the ligation of oligonucleotides via non-enzymatic chemical ligation means was known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the method of ligation disclosed by Balasubramanian et al. (i.e. non-enzymatic chemical ligation) for the method of ligation disclosed by Landegren et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

**12. Claim(s) 20** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al. [US 4,988,617 (1991)] in view of Landegren et al. [US 2005/0287526 (2005)] as applied against Claim 4 above and further in view of Brenner et al. [US 5,846,719 (1998)].

**Claim 20** is drawn to an embodiment of Claim 4 wherein said label is a unique coding sequence of nucleotides in said first oligonucleotide set.

Landegren et al. in view of Landegren et al. reasonably suggest a method for identifying of one or more mutations or SNPs in a genome comprising all of the limitations recited in Claim 20 except these authors do not teach an embodiment wherein the label of said first oligonucleotide set is a unique coding sequence of nucleotides. However, as evidenced by at least Brenner et al. the use of oligonucleotide tags (i.e. a unique coding sequence of nucleotides) as well as labeled oligonucleotide tag complements to detect an oligonucleotide target was known prior to the instant invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the method of detecting taught by Brenner et al. for the method of detection reasonably suggested by the combination of Landegren et al. in view of Landegren et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

### CLAIM OBJECTIONS

**13. Claim(s) 14** is /are is objected to because it is dependent upon a rejected independent base claim, however, Claim 14 would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### CONCLUSION

**14. Claim(s) 1-20** is/are rejected and/or objected to for the reason(s) set forth above.

**15.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

  
ETHAN WHISENANT  
PRIMARY EXAMINER  
Art Unit 1634